

Appl. No. 10/002,842  
Amendment and Response dated February 18, 2004  
Office Action dated November 18, 2003

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1. (Currently Amended) A method for precluding the diagnoses of irritable bowel syndrome and other noninflammatory etiologies ~~distinguishing irritable bowel syndrome from inflammatory bowel disease~~, the method comprising:

obtaining a fecal sample from a person to be diagnosed; and

determining whether said sample contains an elevated level of endogenous lactoferrin, wherein if said sample does contain an elevated level of endogenous lactoferrin, diagnoses of irritable bowel syndrome and other noninflammatory etiologies are substantially precluded.

2. (Original) The method as recited in claim 1, further comprising diluting said fecal sample.

3. (Original) The method as recited in claim 2, wherein said step of diluting said fecal sample comprises diluting said sample to a 1:400 dilution factor.

4. (Currently Amended) The method as recited in claim 1, wherein said endogenous lactoferrin comprises total lactoferrin selected from the group consisting one or more of plasma, bile, leukocytes and mucosal secretions.

5. (Original) The method as recited in claim 1, wherein said endogenous lactoferrin is qualitatively determined.

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6. (Currently Amended) The method as recited in claim 1, wherein said step of determining whether said sample contains an elevated level of endogenous lactoferrin includes contacting said sample with immobilized polyclonal antibodies to human lactoferrin to create an antibody bound ~~treated~~ sample.

7. (Currently Amended) The method as recited in claim 6, wherein said step of determining whether said antibody bound sample contains an elevated level of endogenous lactoferrin further includes contacting said antibody bound~~treated~~ sample with enzyme-linked polyclonal antibodies such that the enzyme-linked polyclonal antibodies are allowed to bind to capture lactoferrin to create an enzyme-linked antibody bound ~~readable~~ sample.

8. (Currently Amended) The method as recited in claim 7, wherein said step of determining whether said enzyme-linked antibody bound sample contains an elevated level of endogenous lactoferrin further includes determining an optical density of said readable sample at 450 nm, wherein said optical density corresponds to a level of endogenous lactoferrin in the enzyme-linked antibody bound sample.

9. (Currently Amended) The method as recited in claim 8, wherein if said optical density of said enzyme-linked antibody bound ~~readable~~ sample is greater than 0.200, said fecal sample contains an elevated level of endogenous lactoferrin.

10. (Canceled)

11. (Canceled)

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12. (Currently Amended) A diagnostic assay for determining whether a fecal sample contains an elevated level of endogenous lactoferrin as compared to a reference value for healthy control subjects, said assay comprising:

obtaining a human fecal sample;

diluting said sample;

contacting said sample with immobilized polyclonal antibodies to endogenous lactoferrin to create an antibody bound treated-sample;

contacting said treated sample with enzyme-linked polyclonal antibodies such that the enzyme-linked polyclonal antibodies are allowed to bind to capture lactoferrin to create an enzyme-linked antibody bound-readable sample; and

determining the optical density of said readable sample at 450 nm to determine whether said enzyme-linked antibody bound-readable sample contains an elevated level of endogenous lactoferrin as compared to a reference value for healthy control subjects.

13. (Currently Amended) The diagnostic assay as recited in claim 12, wherein if said enzyme-linked antibody bound readable-sample contains an elevated level of endogenous lactoferrin, a diagnosis of irritable bowel syndrome is substantially precluded.

14. (Currently Amended) The diagnostic assay as recited in claim 13, wherein if said optical density of said enzyme-linked antibody bound readable sample is greater than or equal to 0.200, said fecal sample contains an elevated level of endogenous lactoferrin as compared to a reference value for healthy control subjects.

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15. (Original) The diagnostic assay as recited in claim 12, wherein said assay comprises an enzyme-linked immunoassay.

16. (Original) The diagnostic assay as recited in claim 12, wherein said endogenous lactoferrin comprises total lactoferrin from one or more of plasma, bile, leukocytes, and mucosal secretions.

17-20. (Canceled)